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#392710 WEMMH PTO/SB/21 (09-04)  
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U.S. Patent and Trademark Office; U.S. DEPARTMENT OF COMMERCE

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<b>TRANSMITTAL FORM</b> (to be used for all correspondence after initial filing)	Application Number	10/811,343	
	Filing Date	March 26, 2004	
	First Named Inventor	Cook, W.	
	Art Unit	1651	
	Examiner Name	Witz, Jean C.	
Total Number of Pages in this Submission	9	Attorney Docket Number	003433-00492

**ENCLOSURES (check all that apply)**

<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached Credit Card Payment Form <input type="checkbox"/> Amendment Response <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement <input type="checkbox"/> Certified Copy of Priority Documents <input type="checkbox"/> Response to Missing Parts/Incomplete Application <input type="checkbox"/> Response to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation, Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) ➤ <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Return Receipt Postcard <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): SB/08a; SB/08b
<b>Remarks</b>		

**SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT**

Firm Name	Woodard, Emhardt, Moriarty, McNett & Henry LLP	
Signature		
Printed Name	Kenneth A. Gandy	
Date	April 20, 2006	Reg. No. 33,386

- ☒ I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as **first class mail** in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.
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April 20, 2006  
Date

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re patent application of:

Cook, W., et al.

Application No. 10/811,343

Filed: March 26, 2004

GRAFT PROSTHESIS, MATERIALS, AND  
METHODS



)  
) Before the Examiner  
) Witz, Jean C.

)  
) Group Art Unit  
) 1651

)  
) April 20, 2006  
)

INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Sir:

1. List of All Patents, Publications, U.S. Applications, or Other Information

Pursuant to the provisions of 37 CFR 1.56, 1.97, and 1.98, Applicant requests consideration of the references listed on the attached PTO/SB/08 form(s) (commonly referred to as a PTO-1449 form) and/or the additional information identified below.

- ☒ I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as **first class mail** in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on the date indicated below.
- ☐ I hereby certify that this correspondence is being deposited with the United States Postal Service as "**Express Mail** Post Office to Addressee" in an envelope addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, Mailing Label No. EV US, on the date indicated below.
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Kenneth A. Gandy

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Signature

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Date

## 2. Enclosed Legible Copies

- a. A legible copy of each foreign patent document and publication listed on the PTO/SB/08 form is enclosed,
- ☐ i. except, a copy is not provided for each reference previously cited by or submitted to the Patent Office in prior U.S. Patent Application Serial No. 09/798,444, filed March 2, 2001 from which the present application claims priority under 35 U.S.C. §120.
- ii. except, a copy is not provided for each cumulative reference and enclosed reference identified below:
- ☐ b. A copy of the specification and drawings for each cited unpublished U.S. application.
- ☐ c. A copy of a Search Report or Written Opinion from a foreign patent office is also enclosed.
- ☐ d. Consideration of the enclosed additional and/or below discussed information is requested.

## 3. Concise Explanation of Relevance for Non-English Language Information

For each non-English language reference listed on the attached SB/08 form(s), reference is made to:

- ☐ 3a. an English language translation submitted herewith,
- ☐ 3b. foreign patent office Search Report (in the English language) submitted herewith,
- ☐ 3c. an English language translation of a foreign patent office Search Report submitted herewith,
- ☐ 3d. the concise explanation contained in the present application at page(s) \_\_\_,
- ☐ 3e. the concise explanation set forth in the attached English language abstract,
- ☐ 3f. a copy of a related patent publication (in the English language) cited herewith,

Foreign Patent Document	Corresponding English Language Patent Document

- ☐ 3g. the following concise explanation: \_\_.

4. Time for Filing

- ☒ 4a. This Information Disclosure Statement is submitted:
- ☐ i. for U.S. national applications or national stage PCT applications (not including CPAs and RCEs), within 3 months of filing or entry into national stage; or
  - ☒ ii. for U.S. national applications, national stage PCT applications, CPAs or RCEs, before the first Office Action on the merits,
- and thus no certification and/or fee is required.
- ☐ 4b. This information Disclosure Statement is submitted after three months from the filing date and after the first Office Action on the merits, but prior to the mailing date of a final Office Action or Notice of Allowance, and thus:
- ☐ i. the statement specified in 37 CFR §1.97(e) is provided below, or
  - ☐ ii. a fee of \$\_\_\_ (set forth in 37 CFR §1.17(p)) is enclosed.
- ☐ 4c. This Information Disclosure Statement is submitted after the mailing date of a final Office Action or Notice of Allowance and prior to payment of the issue fee, and thus:
- ☐ i. the statement specified in 37 CFR §1.97(e) is provided below, and a fee of \$ (set forth in 37 CFR §1.17(p)) is enclosed, or
  - ☐ ii. a Request for Continued Examination (RCE) and fee of 37 CFR §1.17(e) has been filed.
- ☐ 4d. This Information Disclosure Statement is submitted after payment of the issue fee, and thus:
- ☐ i. a Petition to Withdraw from Issue pursuant to 37 CFR §1.313(c)(2) has been filed, and
  - ☐ ii. a Request for Continued Examination (RCE) and fee of 37 CFR §1.17(e) has been filed.

5. Certification- Statement Under 37 CFR 1.97(e)

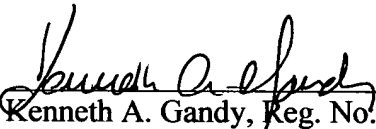
- ☐ 5a. It is hereby certified that each item of information contained in this Information Disclosure Statement was first cited in any communication from a foreign patent

office in a counterpart foreign application not more than three months prior to the filing of this Information Disclosure Statement.

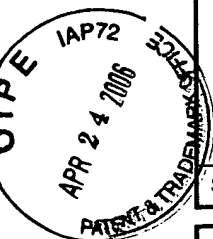
- ☐ 5b. A copy of a dated communication from a foreign patent office which clearly shows the statement is being submitted within three (3) months of the date on the communication is enclosed.
- ☐ 5c. It is hereby certified that no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign patent office in a counterpart foreign application and, to my knowledge after making reasonable inquiry, no item of information contained in this Information Disclosure Statement was known to any individual designated in §1.56(c) more than three months prior to the filing of this Information Disclosure Statement.

The filing of this Information Disclosure Statement shall not be construed as an admission that the information cited is, or is considered to be, material to patentability as defined in §1.56(b). It is believed that no additional fees are required. Should any other fee be required, however, please charge such fee to Deposit Account No. 23-3030, but not to include any payment of issue fees.

Respectfully submitted,

By   
Kenneth A. Gandy, Reg. No. 33,386  
Woodard, Emhardt, Moriarty, McNett & Henry LLP  
111 Monument Circle, Suite 3700  
Indianapolis, Indiana 46204-5137  
(317) 634-3456

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Substitute for form 1449A/PTO

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(Use as many sheets as necessary)

**Complete if Known**

Application Number	10/811,343
Filing Date	March 26, 2004
First Named Inventor	Cook, W.
Art Unit	1651
Examiner Name	Witz, Jean C.
Attorney Docket No.	003433-000492

Sheet 1 of 4

**U.S. PATENT DOCUMENTS**

Examiner Initials*	Cite No. <sup>1</sup>	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code <sup>2</sup> (if known)			
		US- 2,172,903	08/23/1938	Bowen, A.	
		US- 3,562,820	02/16/1971	Bernhard, B.	
		US- 3,632,361	01/04/1972	Battista, O.	
		US- 3,810,473	05/14/1974	Cruz, et al.	
		US- 4,292,972	10/06/1981	Pawelchak, et al.	
		US- 4,347,234	08/31/1982	Wahlig, et al.	
		US- 4,421,947	12/20/1983	Kyle, J.	
		US- 4,578,067	03/23/1986	Cruz, Jr. M.	
		US- 4,606,337	08/19/1986	Zimmermann, et al.	
		US- 4,902,508	02/20/1990	Badylak, et al.	
		US- 4,948,540	08/14/1990	Nigam, A.	
		US- 4,950,483	08/21/1990	Ksander, et al.	
		US- 4,956,178	09/11/1990	Badylak, et al.	
		US- 4,970,298	11/13/1990	Silver, et al.	
		US- 4,994,084	02/19/1991	Brennen, H.	
		US- 5,028,695	07/02/1991	Eckmayer, et al.	
		US- 5,141,747	08/25/1992	Scholz, M.	
		US- 5,206,028	04/27/1993	Li, S.	
		US- 5,219,576	06/15/1993	Chu, et al.	
		US- 5,275,826	01/04/1994	Badylak, et al.	
		US- 5,281,422	01/25/1994	Badylak, et al.	
		US- 5,336,616	08/09/1994	Livesey, et al.	
		US- 5,372,821	12/13/1994	Badylak, et al.	
		US- 5,397,352	03/14/1995	Burres, S.	
		US- 5,445,833	08/29/1995	Badylak, et al.	
		US- 5,446,462	08/29/1995	Cleveland, A.	
		US- 5,451,406	09/19/1995	Lawin, et al.	
		US- 5,457,093	10/10/1995	Cini, et al.	
		US- 5,460,962	10/24/1995	Kemp, P.	
		US- 5,480,424	01/02/1996	Cox, J.	
		US- 5,480,427	01/02/1996	Kelman, et al	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. <sup>1</sup> Applicant's unique citation designation number (optional). <sup>2</sup> See Kinds Codes of USPTO Patent Documents at [www.uspto.gov](http://www.uspto.gov) or MPEP 901.04. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST.16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.

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Substitute for form 1449A/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>			<b>Complete if Known</b>		
			Application Number	10/811,343	
			Filing Date	March 26, 2004	
			First Named Inventor	Cook, W.	
			Art Unit	1651	
			Examiner Name	Witz, Jean C.	
Sheet	2	of	4	Attorney Docket No.	003433-000492

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines Where Relevant Passages or Relevant Figures Appear
		US- 5,489,022	02/06/1996	Baker, B.	
		US- 5,489,261	02/06/1996	Franzblau, et al.	
		US- 5,498,420	03/12/1996	Mentrup, et al.	
		US- 5,489,022	02/06/1996	Baker, B.	
		US- 5,489,261	02/06/1996	Franzblau, et al.	
		US- 5,498,420	03/12/1996	Mentrup, et al.	
		US- 5,501,706	03/26/1996	Arenberg, I.	
		US- 5,514,181	05/07/1996	Light, et al.	
		US- 5,516,395	05/14/1996	Anhauser, et al.	
		US- 5,520,925	05/28/1996	Maser, F.	
		US- 5,531,786	07/02/1996	Perry, et al.	
		US- 5,531,791	07/02/1996	Wolfenbarger, L.	
		US- 5,554,389	09/10/1996	Badylak, et al.	
		US- 5,565,210	10/15/1996	Rosenthal, et al.	
		US- 5,567,806	10/22/1996	Abdul-Malak, et al.	
		US- 5,571,181	11/05/1996	Li, S.	
		US- 5,607,476	03/04/1997	Prewett, et al.	
		US- 5,607,590	03/04/1997	Shimizu, Y.	
		US- 5,641,518	06/24/1997	Badylak, et al.	
		US- 5,645,860	07/08/1997	Knapp, et al.	
		US- 5,695,998	12/09/1997	Badylak, et al.	
		US- 5,711,969	01/27/1998	Patel, et al.	
		US- 5,755,791	05/26/1998	Whitson, et al.	
		US- 5,762,966	06/09/1998	Knapp, et al.	
		US- 5,782,914	07/21/1998	Schankereli, K.	
		US- 5,866,414	02/02/1999	Badylak, et al.	
		US- 5,885,619	03/23/1999	Patel, et al.	
		US- 5,955,110	09/21/1999	Patel, et al.	
		US- 6,099,567	08/08/2000	Badylak, et al.	
		US- 6,206,931	03/27/2001	Cook, et al.	
		US- 6,475,232	11/05/2002	Babbs, et al.	

Examiner Signature		Date Considered	
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Substitute for form 1449/PTO  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>  <i>(Use as many sheets as necessary)</i>				<b>Complete if Known</b>	
				Application Number	10/811,343
				Filing Date	March 26, 2004
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				Art Unit	1651
Examiner Name	Witz, Jean C.				
Sheet	3	of	4	Attorney Docket No.	003433-000492

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Application of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
		Country Code <sup>3</sup> -Number <sup>4</sup> - Kind Code <sup>5</sup> (if known)				
		WO 95/22611	08/24/1995	The Regents of the University of Michigan		<input type="checkbox"/>
		WO 96/24661	08/15/1996	Purdue Research Foundation, et al.		<input type="checkbox"/>
		WO 96/25179	08/22/1996	Purdue Research Foundation, et al.		<input type="checkbox"/>
		WO 96/31157	10/10/1996	Organogenesis, Inc.		<input type="checkbox"/>
		WO 96/32146	10/17/1996	Advanced Cytometrix, Inc.		<input type="checkbox"/>
		WO 98/22158	05/28/1998	Cook Biotech, Inc.; Med Institute, Inc.		
		WO 98/25636	06/18/1998	Purdue Research Foundation		
		WO 98/25637	06/18/1998	Purdue Research Foundation		
		WO 98/26291	06/18/1998	Purdue Research Foundation		
		WO 00/32250	06/08/2000	Cook Biotech, Inc.		

Examiner Signature		Date Considered	
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			Examiner Name	Witz, Jean C.	
Sheet	4	of	4	Attorney Docket No.	003433-000492

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s) publisher city and/or country where published	T <sup>2</sup>
		American National Standard, ANSI/AAMI 10993-1:1994. "Biological Evaluation of Medical Devices—Part 1: Guidance on Selection of Tests". Association for the Advancement of Medical Instrumentation. pp. 9-17.	<input type="checkbox"/>
		BLOCK, S. "Peroxygen Compounds", <i>Disinfection, Sterilization and Preservation</i> , 5 <sup>th</sup> Edition 2001. pp. 185-204. Lippincott Williams & Wilkins, Philadelphia, PA.	<input type="checkbox"/>
		CLARKE, K.M., et al. "Intestine Submucosa and Polypropylene Mesh for Abdominal Wall Repair in Dogs". <i>The Journal of Surgical Research</i> . Jan. 1996. Vol. 60, No. 1. pp. 107-114.	<input type="checkbox"/>
		DENTON, F.W., "Chlorhexidine", <i>Disinfection, Sterilization and Preservation</i> , S. Block, editor, 5 <sup>th</sup> Edition 2001. pp. 321-336. Lippincott Williams & Wilkins, Philadelphia, PA.	<input type="checkbox"/>
		"Guideline on Validation of the Limulus Amebocyte Lysate Test as an End-Product Endotoxin Test for Human and Animal Parenteral Drugs, Biological Products, and Medical Devices". Dec. 1997. Center for Drug Evaluation and Research, Center for Biologic Evaluation and Research, Center for Devices and Radiological Health, and Center for Veterinary Medicine.	<input type="checkbox"/>
		KROPP, B.P., et al. "Experimental Assessment of Small Intestinal Submucosa as a Bladder Wall Substitute". <i>Urology</i> . Sept. 1995. Vol 46, No. 3. pp. 396-400.	<input type="checkbox"/>
		KROPP, B.P., et al. "Regenerative Urinary Bladder Augmentation Using Small Intestinal Submucosa: Urodynamic and Histopathologic Assessment in Long-Term Canine Bladder Augmentations". <i>The Journal of Urology</i> . June 1996. Vol. 155, No. 6. pp. 2098-2104.	<input type="checkbox"/>
		PREVEL, C.D., et al. "Small Intestinal Submucosa: Utilization for Repair of Rodent Abdominal Wall Defects". <i>Annals of Plastic. Surgery</i> . Oct. 1995. Vol. 35, No. 4. pp. 374-380.	<input type="checkbox"/>
		PREVEL, C.D., et al. "Small Intestinal Submucosa: Utilization as a Wound Dressing in Full-Thickness Rodent Wounds". <i>Annals of Plastic. Surgery</i> . Oct. 1995. Vol. 35, No. 4. pp. 381-388.	<input type="checkbox"/>

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<sup>2</sup>Applicant is to place a check mark here if English language Translation is attached.